September 24, 2008

Wendy H. Koch, Ph.D.
The MBOCA Consortium
Epona Associates, LLC
56 River Road Studio 3
Willington, CT 06279

Dear Dr. Koch:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 4',4'-methylenebis(2-chlorobenzenamine), posted on the ChemRTK HPV Challenge Program Web site on February 7, 2006. I commend the MBOCA Consortium for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that the Consortium advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. EPA has moved energetically from the HPV Challenge Program to the Chemical Assessment and Management Program, or ChAMP (www.epa.gov/champ) and is relying on Challenge chemical sponsors to provide, as expeditiously as possible, the data that are the key to this effort.

Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov. If you have any questions about this response, please contact me at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Mark W. Townsend, Chief
HPV Chemicals Branch

Enclosure

cc: O. Hernandez
R. Lee
J. Willis

EPA Comments on Chemical RTK HPV Challenge Submission:
4,4'-Methylenebis(2-chlorobenzenamine)

Summary of EPA Comments

The sponsor, the MBOCA Consortium, submitted a test plan and robust summaries to EPA for 4,4'-methylenebis(2-chlorobenzenamine)(MBOCA, CAS No. 101-14-4) dated 12/29/05. EPA posted the submission on the ChemRTK HPV Challenge Web site on 02/07/06. Additional submitted data dated July 3, 2007 were posted on the HPV Challenge Web site on August 30, 2007.

EPA has reviewed this submission and has reached the following conclusions.

1. Physical Chemical Properties. Adequate data are available for these endpoints for the purposes of the HPV Challenge Program.

2. Environmental Fate. Adequate data are available for these endpoints for the purposes of the HPV Challenge Program.

3. Health Effects. Adequate data are available for these endpoints for the purposes of the HPV Challenge Program. A robust summary is needed for the combined screening test (OECD TG 422).

4. Ecological Effects. Data submitted for fish and invertebrates are missing elements critical for evaluation of adequacy. Data for algae are inadequate because a definitive value for EC_{50} was not achieved.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the 4,4'-Methylenebis(2-Chlorobenzenamine) Challenge Submission

Test Plan

Physical Chemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

Adequate data are available for these endpoints for the purposes of the HPV Challenge program.

Melting point. One of the values provided, 110 □C, cited as a calculated value, is actually an experimental value obtained from the modeling software database and should be re-labeled as such.

Boiling point. The submitter provided only a calculated boiling point of 378.9 □C. Because it exceeds the HPV 300 □C cutoff for measured values it is adequate for this endpoint.

Environmental Fate (photodegradation, stability in water, biodegradation and fugacity)

Adequate data are available for these endpoints for the purposes of the HPV Challenge program.

Photodegradation. The data provided by the submitter for atmospheric oxidation are adequate for the purposes of the HPV Challenge Program. However, EPA recommends that the submitter comment on the potential for this chemical to undergo direct photolysis.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity and reproductive/developmental toxicity)

Adequate data are available for these endpoints for the purposes of the HPV Challenge Program. A robust summary is needed for the combined repeated-dose, reproductive, and developmental toxicity screening test (OECD TG 422).

Ecological Effects (fish, invertebrates and algae)

Fish and invertebrates. EPA cannot evaluate the limited acute data in the submitted summaries (see next section) and reserves judgment pending receipt of adequately enhanced robust summaries.

Algae. The submitted study is inadequate because test concentrations were too low to achieve an appropriate endpoint value. The submitter needs to provide adequate data.

Specific Comments on the Robust Summaries

In general, the robust summaries lacked adequate experimental details.

Environmental Fate

Fugacity. The fugacity robust summary needs to include the inputs to the model.

Ecological Effects

Fish and invertebrates. Missing critical data elements include: pH, water hardness, temperature, dissolved oxygen, type of test (flow-through or static renewal), measured or nominal concentrations, type of test containers, study observations, test chemical preparation, number of tests, number of replicates per test, test renewals, and whether test concentrations were mean-measured.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.